Reference

1. Bhosale Neelambari, Shagoofa Nigar, Soma Das, Uma Divate, Pathik Divate, Protection of human research participants: accreditation of programmes in the Indian context, (2014), Indian Journal of Medical Ethics Vol XI No 1 January-March .
2. C M Gulhati , Needed: closer scrutiny of clinical trials,(2004) Indian Journal of Medical Ethics Vol I No 1 January- March.
3. Charles Weijer, The Ethical Analysis of Risk, (2000) Journal of Law , Medicine & Ethics, 28: 344 -361.
4. D.J Rothman, Ethics and Human Experimentation: Henry Beecher revisited,(1987) N Engl J Med 1987: 317: 1195-9.
5. Das Ranjan, PN Das, Biomedical Research Methodology, Including Biostatistical Applications,(2011) Jaypee Brothers Medical Publishers (P) Ltd.
6. Decosta, Aet al. Community based trials and informed consent in rural north India,(2004) J Med Ethics, Vol 30.
7. Devaiah Vishwas H , Impact of bioethics on patentability of inventions,(2010) Indian Journal of Medical Ethics Vol VII No 1 January - March.
8. Eckstein Sue , Ethical issues in research on humans,(2001) Indian Journal of Medical Ethics, Issues in Medical Ethics, IX(1), January-March.
9. Fulford K, Howse K Ethics of research with psychiatric patients: principles ,problems and the primary responsibility of researchers,(1993) J Med Ethics: 19;85-91.
10. Godard B, Schmidtke J, Cassiman JJ, Aymé S (2003) Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. Eur J Human Genet 11 (Suppl 2): 88–122 .
11. H.J.J Leenen, Genetics, Confidentiality and research, (2000) European Journal of Health Law, Vol.7.
12. J.A.Kegley,Genetics Decision – making : A Template for problems with informed consent;(2002) Medical Law 21 , 459-71.
13. J.S.Mill, ‘ON Liberty’ in J.Gray (ed.), On Liberty and Other Essays.(1991) (Oxford: Oxford University Press), p.5, 75-85.

14. Kammen Jessika van, Informed Consent in Clinical Trials,(2000) IJME July- Sept. 8(3).
15. Kang Gagandeep, Putting patients first: draft guidelines for compensation for research-related injury in clinical trials in India,(2012) Indian Journal of Medical Ethics Vol IX No 2 April - June .
16. Kundapura Shankar V, Thirtha Poovaiah, Ravindra B Ghooi, The Big Cs Of The Informed Consent Form: Compliance And Comprehension,(2013) Indian Journal Of Medical Ethics Vol X No 4 October-December .
17. L A Jansen. Mindsets, informed consent, and research, Hastings Cent Rep. (2014) Jan–Feb; 44(1):25–32. doi: 10.1002/ hast.237.
18. Laura Weiss Rebort 'Informed Consent' and the capacity for voluntarism.(2002) Am J Psychiatry 159: 705-712, May.
19. Len Doyal , Informed consent in medical research: Journals should not publish research to which patients have not given fully informed consent–with three exceptions, (1997) *BMJ* ;314:1107.
20. Lidz cw .Appelbaum PS, Meisel A. Two models of implementing informed consent.(1988), Arch .Intern .Med 88; 148: 1385-1389.
21. Lin Ruth Mack, The Declaration of Helsinki: another revision, (2009),Indian Journal of Medical Ethics Vol VI No 1 January-March.
22. Marilyn J. Field and Richard E. Berman, (eds), The Ethical Conduct of Clinical Research Involving Children, (2004) Committee on Clinical Research Involving Children .
23. Mohapatra Prasanta Raghab, Deepak Aggarwal, Responding to deaths during a clinical trial,(2009), Indian Journal of Medical Ethics Vol VI No 1 January-March.
24. Muthuswamy Vasantha, The new 2013 seventh version of the Declaration of Helsinki – more old wine in a new bottle?,(2014) Indian Journal of Medical Ethics Vol XI No 1 January-March .
25. Nair Mohanan, Douglas K Martin, Concerns about ethical review of health research ,(2004) India Indian Journal of Medical Ethics Vol I No 4 October–December .
26. P.M. McNeill The ethics and politics of human experimentation.(1993) Cambridge : Cambridge University Press, 17-36,53-115.

27. R Al-Shahi, Vousden C, Warlow C, Bias from requiring explicit consent from all participants in observational research: prospective, population based study.(2005) *BMJ* ;331:942
28. Richard E. Ashcroft, The Ethics and Governance of Medical Research: what does regulation have to do with morality?(2003), New Review of Bioethics, Vol. 1, No. 1, 41–58, November
29. S Nundy, Gulhati CM. A New Colonialism? — Conducting Clinical Trials in India, (2005) N Eng J Med ; 352: 1633-6.
30. Shilling V, Young B, How do parents experience being asked to enter a child in a randomised controlled trial?,(2009), *BMC Med Ethics*, Feb 16; 10:1.
31. Sisira Siribaddana Wasantha Bandara, Clinical trials in Sri Lanka: New Act at the behest of the pharmaceutical industry?, (2013) Indian Journal of Medical Ethics Vol X No 4 October-December p. 268]
32. Stewart,Cameron and paul Biegler "A Primer on the Law of competence to refuse Medical Treatment." (2004) Australian Law Journal 78 ,325-342.
33. T.L Beauchamp,& L.Walters, eds., Contemporary Issues in Bioethics,(1989) 3rd edition, Calif. Wadsworth Publishing Company.
34. Tharyan Prathap, Ethics committees and clinical trials registration in India: opportunities, obligations, challenges and solutions ,(2007) Indian Journal of Medical Ethics Vol IV No 4 October-December .
35. Tharyan Prathap, Strategies to increase the number clinical trials that are recruiting children in India registered on the Clinical Trials Registry-India (CTRI), Report submitted to HQ/RPC Research Policy and Cooperation: WHO.
36. Tomossy George F. and David N. Weisstub (Ed) , Human Experimentation and Research, Ashgate, Hans Jonas (1969), 'Philosophical Reflections on Experimenting with Human Subjects', Daedalus, 98, pp.219- 47.
37. Tomossy George F. and David N. Weisstub (Ed) , Human Experimentation and Research, Ashgate, Alexander Morgan Capron (1999), 'Is National , Independent Oversight Needed for the Protection of Human Subjects?'Accountability in Research 7, p.283-92.
38. Tomossy George F. and David N. Weisstub (Ed) , Human Experimentation and Research, Ashgate, ,Paul R. Benson, The Social Control of Human Biomedical

Research: An Overview and Review of the Literature. Social Science and Medicine, (1989) 29, pp.1-12.

39. Tomossy George F. and David N. Weisstub (Ed) , Human Experimentation and Research, Ashgate, Eric M. Meslin, Heather J. Sutherland, James V. Lavery and James E. Till, (1995) 'Principlism and the Ethical Appraisal of Clinical Trials', Bioethics, 9, pp.399-418.
40. Weir RF. Selective Non treatment of Handicapped Newborns (1984): Moral Dilemmas in Neonatal Medicine, New York, NY: Oxford University Press.

****